UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
CONGRESSIONAL AND
INTERGOVERNMENTAL
RELATIONS

The Honorable Thomas R. Carper
Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Senator Carper:

On behalf of the U.S. Environmental Protection Agency, I am writing in response to your letters dated July 5, 2018 and March 4, 2019, regarding the Integrated Risk Information System (IRIS) program's formaldehyde assessment.

To date, the EPA has provided multiple responsive actions to inquiries regarding the IRIS program. Approximately a week after receiving the letter, on March 13, 2019, the Agency provided the Committee with a briefing on the reorganization of the Office of Research and Development (ORD) by ORD Principal Deputy Assistant Administrator for Research and Development and Science Advisor Jennifer Orme-Zavaleta and other EPA staff. This briefing included a discussion about the impacts of the reorganization on the IRIS program. Additionally, the EPA provided Principal Deputy Assistant Administrator Orme-Zavaleta to testify at a hearing on the IRIS program on March 27, 2019, before the House Committee on Science, Space, and Technology Subcommittee on Oversight and Investigations and Subcommittee on Environment. At the hearing Principal Deputy Assistant Administrator Orme-Zavaleta answered questions for an extensive amount of time on issues directly presented in the Committee's March 4, 2019 letter and articulated the decision-making process behind the IRIS assessment prioritization, which the Committee further inquired about in an April 3, 2019 letter. The Agency has also provided the Committee with a briefing on the fiscal year (FY) 2020 ORD budget on April 2, 2019, which included extensive discussion regarding the funding and future of the IRIS program.

The EPA takes a "One EPA" approach to provide the scientific and technical support that EPA programs, Regions, states, and tribes need to carry out the Agency's mission to protect human health and the environment. The IRIS program is operated from ORD, and both the IRIS program and ORD are dedicated to supporting other Agency, Regional, state, and tribal programs—such as water, air, chemicals, land, and pesticides. ORD scientists routinely collaborate with colleagues in other Agency programs, including those involved with the Toxic Substances Control Act (TSCA), thereby leveraging ORD's scientific expertise and allowing the EPA to use the best available science in its decision making. In 2016, when the Frank R.

Lautenberg Chemical Safety for the 21st Century Act was passed, the IRIS program made assisting the Office of Chemical Safety and Pollution Prevention (OCSPP) with TSCA implementation a high priority.

There are four main components of risk assessment: hazard identification, dose-response assessment, exposure assessment, and risk characterization. IRIS assessments include the first two steps of the risk assessment process: hazard identification and dose-response. Hazard identification identifies the health outcomes associated with a chemical. Dose-response assessment characterizes the quantitative relationship between potential chemical exposures and health hazards and is used to derive, when appropriate, toxicity values. The information provided by IRIS can be combined with exposure assessments to inform risk assessments conducted by EPA programs, Regions, states, and tribes. IRIS assessments are not regulations and should not be used in isolation and without the consideration of potential exposures and without a regulatory context. IRIS assessments, if developed in accordance with regulatory requirements, can provide, in whole or in part, a scientific foundation for assessing risk and decision making to protect human health across the EPA under an array of environmental laws. The process for completing an IRIS assessment can result in changes between a draft and final IRIS report. As such, a draft IRIS assessment should not be used as the basis for a decision.

Over the course of its existence, the IRIS program has routinely received input and review from a number of external analyses and organizations. In 2011 and 2014, the National Academy of Sciences (NAS) issued reports outlining recommendations to improve the IRIS program by adopting systematic review, a method of conducting a standardized literature-based assessment and quality review known for the transparency and rigor it brings to the process. Additionally, Congress has recognized problems within the IRIS program and weighed in with specific direction on how the EPA should work with NAS. In fiscal year 2017, Congress passed legislation which directed the EPA to contract with NAS to review whether NAS's recommendations were being implemented. In April 2018, the NAS issued a consensus report on the progress of the IRIS program. In its overall conclusions, the NAS committee reported, "The committee is encouraged by the steps that EPA has taken, which have accelerated during the last year under new leadership. It is clear that EPA has been responsive and has made substantial progress in implementing National Academies recommendations."

While the NAS reviewed the plans and intent of the proposed changes by the IRIS program, the Agency recognizes that there has yet to be an assessment produced for public comment that is fully consistent with the NAS recommendations made in its 2011 and 2014 reports.

The Government Accountability Office (GAO) has also provided input to improve the IRIS program. This input from Congress included suggestions to address timeliness, improve transparency, and address process challenges. In their recent audit report, GAO found that the IRIS program has made improvements and has demonstrated the impact of the corrective actions on IRIS workflow, productivity, and impact. Additionally, the Agency recognizes that due to the history of the IRIS program's lack of productivity, the program has been listed on GAO's "high risk" list since 2009.

In the wake of that input and internal program audits, the IRIS program has modernized its process and workflows by incorporating project and program management to better manage staff and resource commitments. In addition, it has moved away from one-size-fits-all assessments to a mixed portfolio of chemical evaluation products. It has also optimized the use of a variety of specialized systematic review software tools to increase efficiency and promote greater transparency by making the underlying assessment information more accessible to the public. With these changes, it is hoped that a large segment of the assessment portfolio can be completed in 1-3 years instead of 3-15 years for the one size-fits-all model. As the GAO audit report indicates, preparation of several recent draft protocols has taken months, not years. These are significant improvements that have helped address GAO's input regarding the timeliness, transparency, and process of IRIS assessments.

Even as the IRIS program modernizes, it has continued to adhere to the "IRIS Process," which includes intra- and inter-agency review, public comment, and peer review. The IRIS Process has been carefully negotiated with its stakeholder communities inside and outside the federal government. Enclosed is a presentation that was provided to NAS on the advances made to the IRIS program that also details the extensive steps that remain in the review process before an assessment can be deemed final and ready for publication.

The IRIS program has also invested in extensive staff training across its organization to energize this culture of change and ensure new processes are successful. Continuous staff training has been incorporated into the workflow, and the use of specialized software tools make it possible to bring more of the work in-house using existing full-time equivalent (FTE) staff with reduced reliance on contract and extramural resources. It allows the IRIS program to stabilize the quality of work products and prepare for fluctuating workload scenarios. Despite these improvements to the IRIS program, the Agency still recognizes that further changes need to be implemented in order to allow the IRIS program to effectively support all programs, Regions, states, and tribes.

Another major change this Administration has implemented is to ensure that the IRIS program is always working on the Agency's highest priorities. Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

Through this new process, EPA programs and Regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and Region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. Based on that input, this prioritization process identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFAS), and vanadium. The IRIS program will conduct

this same formal request and prioritization process annually, but programs and Regions are still able to identify and nominate additional chemicals at any time.

Not only does this improve the scope of IRIS assessments and help the IRIS program prioritize its activities, it also reinforces accountability between the requesting program and IRIS. An added benefit of this new process is that it should result in a reduction in the length of time it takes to produce assessments because each assessment should be tailored to the program needs—called fit-for-purpose assessments.

As you are aware, there is currently an assessment of formaldehyde toxicity in the IRIS program database that was completed in 1990. The EPA released a new draft formaldehyde IRIS assessment in 2010 that updated this assessment from 1990. However, in 2011, a NAS peer review panel criticized aspects of the 2010 draft formaldehyde assessment and, feeling so strongly about their criticisms, the NAS panel went beyond the scope of its charge and made multiple recommendations on how to improve not just the formaldehyde IRIS assessment but the entire IRIS program. The additional review of the IRIS program by a NAS peer review panel in 2014 provided additional recommendations about the use of systematic review approaches that were also pertinent to the formaldehyde assessment. As described above, the IRIS program is addressing these recommendations programmatically but has yet to issue a final assessment reflecting all of these improvements.

Because IRIS assessments are major investments in both time and resources, it is important to ensure IRIS program activities are addressing the Agency's IRIS priorities. To further enable the IRIS program to meet these needs, the EPA paused all IRIS assessments and instituted a process where EPA program offices and Regions identified their priorities for IRIS assessments. As detailed above, through this prioritization process, EPA program offices identified eleven priority chemicals for IRIS assessments. However, based on the comprehensive input received from the program offices and Regions, formaldehyde was not identified as a final top priority for the IRIS program. As detailed by Principal Deputy Assistant Administrator Orme-Zavaleta in her testimony at a hearing on the IRIS program on March 27, 2019, before the House Committee on Science, Space, and Technology Subcommittee on Oversight and Investigations and Subcommittee on Environment, no programs identified formaldehyde as a priority in their final list of priority chemicals. Programs with regulatory duties were directed to submit forms of priority chemicals for review. Other offices without these duties could submit a form through the Deputy Administrator's Office.

Despite many reports that the IRIS formaldehyde study is complete and ready for release, there are still additional steps in the "IRIS process" that have not been completed and that are required before a final assessment is available. Necessary next steps would include a multi-tiered process that provides structured opportunities for intra- and inter-agency engagement throughout the assessment development process before and after release for public review and comment. Substantial improvements could occur during this part of the process to address the comments and input. The assessments are complex and involve multidisciplinary evaluations of scientific information, developed through a transparent and systematic process including peer review.

As you are aware, completion of the IRIS formaldehyde assessment has not prevented the EPA from taking action to regulate formaldehyde emissions. The Formaldehyde Emission Standards for Composite Wood Products Act of 2010 established emission standards for formaldehyde from composite wood products, and in December 2016, the EPA finalized a rule regulating formaldehyde emissions from hardwood plywood, particleboard, and similar composite wood products. The EPA has also issued regulations for a range of formaldehyde combustion sources under the National Emission Standards for Hazardous Air Pollutants (NESHAP) program. Under the Office of Air and Radiation (OAR) National-Scale Air Toxics Assessment (NATA) program, the EPA has conducted an emissions inventory for a variety of hazardous air pollutants (HAPs), including formaldehyde.

The recent changes to TSCA in 2016 have also led the Agency to reexamine the most appropriate programs for efficient and effective assessment of chemicals through its statutory obligations and other methods. On March 20, 2019, the EPA published a list of 40 chemicals for which the Agency initiated the prioritization process, a new process through which the EPA designates chemical substances as high priority or low priority for risk evaluation under the amended TSCA. During the prioritization process, the public has several opportunities to submit relevant information on these chemicals, such as information on the conditions of use, hazards, and exposure. A docket has been opened for each of the 40 chemicals. The publication of this list in the *Federal Register* initiated a 90-day public comment period and also activated a statutory requirement for the EPA to complete the nine-to-twelve month prioritization process, culminating in the designation of 20 chemicals as high priority for risk evaluation and 20 chemicals as low priority for risk evaluation, by December 2019.

One of the chemicals identified as a candidate for high-priority designation is formaldehyde. Moving forward with a risk evaluation for formaldehyde under TSCA does not mean that the formaldehyde work done under IRIS will be lost. In fact, all the work done by the IRIS program will inform the Agency as it evaluates formaldehyde under TSCA.

By conducting a risk evaluation under TSCA, the Agency will be able to take subsequent regulatory steps, if the EPA determines that the chemical will present an unreasonable risk of injury to health or the environment under its conditions of use. The IRIS program was not mandated by Congress and does not provide authority to take these regulatory steps. As noted earlier, IRIS is only half of a risk assessment (no exposure or risk characterization) and thus a risk assessment has no immediate impact on minimizing or eliminating risk until applied in a regulatory context. Under TSCA, when prioritization is complete, chemicals designated as high priority will begin a three to three-and-a-half year risk evaluation process to determine if the chemical, under its conditions of use, presents an unreasonable risk to health or the environment. If unreasonable risk is found under TSCA, the EPA is then required to take steps, by issuing a proposed regulation within one year (subject to extension), to mitigate the unreasonable risk.

The 20 high priority candidate chemicals include seven chlorinated solvents, six phthalates, four flame retardants, formaldehyde, a fragrance additive, and a polymer pre-curser.

Despite repeated claims, the EPA is not shifting full-time equivalent (FTE) staff from the IRIS program to OCSPP, consistent with the Explanatory Statement in appropriations legislation. As

the Agency has explained previously, the IRIS program will continue to operate in ORD. The IRIS program is funded through the Human Health Risk Assessment Program (HHRA). As noted above, technical support is among ORD's responsibilities and it provides this support to all programs, Regions, states, tribes, and other stakeholders.

IRIS program staff continue, consistent with historical practice, to provide support to TSCA activities, but that support fluctuates depending on the TSCA timeline and the specific expertise needed at any given time. From October 2017 to March 2018, looking across all IRIS program staff, excluding staff on formal detail to OCSPP, the EPA conservatively estimates that IRIS program staff spent approximately 3 percent of their total work time, on average, supporting TSCA risk evaluation development. The IRIS program is using project management tools to track this effort, in conjunction with the IRIS assessments prioritized for FY 2019.

It is also important to distinguish between individual level of efforts, which may rise for discrete periods of time, with overall levels of support by the IRIS program. For example, in December 2018, there was a high level of activity to support TSCA risk evaluation development, and at certain points during this time, an individual expert in the IRIS program may have spent 25-50 percent of their time providing this support. Even during that month of high activity, only approximately 14 percent of time across all IRIS program staff was related to support for TSCA risk evaluation development.

In FY 2018, four ORD staff were detailed to OCSPP to work specifically on TSCA risk evaluations on detail positions—three full-time and one part-time. Of these, one detailee elected to remain in OCSPP working on the TSCA risk evaluations. These detail positions provided beneficial training to IRIS program staff to become familiar with the TSCA risk evaluation workflow.

Additionally, in FY 2018 and FY 2019 (through Q2), five staff from the Safer Choice program in the Chemistry, Economics, and Sustainable Strategies Division (CESSD) of the Office of Pollution Prevention and Toxics (OPPT), have been detailed to other OPPT organizations to support the TSCA New and Existing Chemicals Program. Details began in early 2018. The employees have been detailed full time since the details began, equaling approximately 4.5 FTE in aggregate over FY 2018 and FY 2019 to date. In addition to the detailees, another four CESSD staff from the Safer Choice Program support TSCA implementation through the Safer Chemical Ingredient List, which informs Low Priority Chemicals Prioritization efforts; that work has amounted to approximately 0.4 FTE in FY 2019. Staff detailed to or supporting the TSCA program from the Safer Choice Program have their salary and benefit costs directly charged to the Chemical Risk Review and Prevention (TSCA) Program funding.

The EPA acknowledges that the IRIS program still has work to do, and we are committed to addressing the recommendations made by the NAS and GAO. With completion of the formal request and prioritization process, the public and stakeholders can expect to see IRIS assessments move forward. In March, the IRIS program released a systematic review protocol for the hexavalent chromium assessment for public comment (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=343950). Last month, the IRIS program released its "Updated Problem Formulation and Systematic Review Protocol for the

Inorganic Arsenic Assessment" for a 30-day public comment period (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=343951). The protocol was then discussed by the NAS at a public meeting on July 16, 2019. And finally, we anticipate the release of the IRIS program's systematic review protocol for PFAS compounds this summer. The Agency will be sure to keep the Committee updated with its progress. As the IRIS program moves forward to develop assessments, the Agency is confident that it will be able to address the open recommendations and identified concerns.

The formal request and prioritization process, along with the improvements IRIS has made in the past few years to address NAS and GAO recommendations, will allow IRIS to be an efficient and effective program that provides the Agency's IRIS users with the science needed to help fulfill statutory mandates to protect human health and the environment.

Please note that this production contains documents that reveal internal Agency information. Therefore, we have added a header and footer to these documents that reads "Internal Document of the U.S. EPA; Disclosure Authorized Only to the U.S. Senate Committee on Environment and Public Works for Oversight Purposes." Through this accommodation, the EPA does not waive any confidentiality interests in these documents or similar documents in other circumstances.

The EPA respectfully requests that the Committee and staff protect the documents and the information contained in them from further dissemination. Should the Committee determine that its legislative mandate requires further distribution of this confidential information outside the Committee, we request that such need is first discussed with the EPA to help ensure the Executive Branch's confidentiality interests are protected.

EPA recognizes the importance of the Committee's need to obtain information necessary to perform its legitimate oversight functions and is committed to continuing to work with your staff on how best to accommodate the Committee's interests. In order to efficiently address further questions, the EPA would welcome the opportunity to brief Committee staff on the issues raised in your letter. If you have further questions, you may contact me, or your staff may contact Travis Voyles in the EPA's Office of Congressional and Intergovernmental Relations at Voyles.Travis@epa.gov or (202) 564-6399.

Sincerely,

Joseph A. Brazauskas
Acting Associate Administrator

Enclosure

cc: The Honorable John Barasso, Chairman